K061766

510(k) SUMMARY

Percutaneous Systems, Inc.'s Expressway Intermittent Catheter

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Percutaneous Systems, Inc.
1300 Crittenden Lane, Suite 101
Mountain View, CA 94043-1359

Phone: (650) 969-8800
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Contact Person: Thomas Lawson

Date Prepared: March 1, 2007

Common or Usual Name

Urology catheter

Classification Name

G-U Devices

Predicate Device

SLIP Urology Catheter, Percutaneous Systems, Inc.

Intended Use

The Expressway Intermittent Catheter is intended to provide an intermittent pathway for draining fluids from and instilling fluids into the bladder. The device is indicated for providing lubricity during the catheter's advancement.

Technological Characteristics

The Expressway intermittent catheter consists of a film membrane pre-loaded within the lumen of a catheter.

Performance Data

Not required.

K061766

Substantial Equivalence

The Expressway Intermittent Catheter has the same intended use, indications for use, principles of operation and technological characteristics as the predicate device. Thus, the Expressway Intermittent Catheter is substantially equivalent to the cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Thomas Lawson, Ph.D.
Vice President, Clinical & Regulatory Affairs
Percutaneous Systems, Inc.
1300 Crittenden Lane, Suite 101
MOUNTAIN VIEW CA 94043

MAR 0 9 2007

Re: K061766
Trade/Device Name: Expressway Intermittent Catheter, Models IC 2410-06 through IC 2440-18
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: February 13, 2007
Received: February 15, 2007

Dear Dr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K061766

Device Name: Expressway Intermittent Catheter

Indications for Use:

The Expressway Intermittent Catheter is intended to provide an intermittent pathway for draining fluids from and instilling fluids into the bladder. The device is indicated for providing lubricity during the catheter's advancement

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061766